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SEP 3 1996

# SUNRISE

TECHNOLOGIES

510(k) Summary

## SUMMARY OF SAFETY AND EFFECTIVENESS

Regulatory Authority: Safe Medical Devices Act of 1990, Section 513.  
21 CFR 807.92

Company Name: Sunrise Technologies, Inc.  
47257 Fremont Blvd.  
Fremont, CA 94538  
(510) 623-9001

Device Name: Sunrise Curing Lamp

Predicate Device: ADT 1000 Plasma Arc Curing System

Device Description: The Sunrise Curing Lamp is a high intensity light source that is filtered and transmitted through a liquid optical fiber to the tooth for curing of composite resins.

Intended Use: The Sunrise Curing Lamp is indicated for use in curing of composite resin materials for restoration of cavity preparation, curing of bonding materials, and any application where a conventional halogen curing lamp would be used.

Comparison With Predicate Device: See accompanying table.

Additional Information: A bibliography of selected articles is available from Sunrise Technologies, Inc. upon request.

Conclusion: Based on the favorable comparison of the technical performance specifications of the Sunrise Curing Lamp with the ADT 1000 Plasma Arc Curing Lamp, the company concludes that these substantially equivalent devices are safe and effective when used by properly trained individuals.

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Sunrise Technologies, Inc.

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Date

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Sunrise Curing Lamp 510(k)

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#### IV: **EQUIVALENCE**

##### A. General

The Sunrise Curing Lamp is substantially equivalent to the ADT 1000 Plasma Arc Curing System marketed by American Dental Technologies, Inc., San Carlos, California. The table below compares the features of these two equivalent systems. Please see Section 15 for a copy of predicate device ADT 1000 Plasma Arc Curing System Operator Manual.

Features	ADT 1000 Plasma Arc Curing System	Sunrise Curing Lamp
Power Input	Provided by KCP 1000	115V~, 50/60 Hz, 2A 230 V~, 50/60 Hz, 1A
Light Source	Xenon short arc lamp	Xenon short arc lamp
Curing Power Output	270mW to 850mW	400mW $\pm$ 50mW
Duration	10 sec. to 25 sec.	Default 10 sec. Adjustable 1 to 99 sec.
Optical Bandwidth	430nm to 500nm	420nm to 500nm
Beam Delivery	Liquid Light Guide, 1.7m Length. Rotating Handpiece. Fiber-optic Tip, 6.5 mm dia.	Liquid Light Guide, 1.8m Length Rotating Handpiece Fiber-optic Tip, 6mm dia.
User Controls	Footswitch (for KCP 1000)	<u>Power ON/OFF</u> - Switch on front panel <u>Duration set</u> - Increment/ decrement touchpads on front panel <u>Light ON/OFF</u> - Switch on handpiece
Calibration	Port on front panel.	Prompted at each power ON sequence Port on front panel
Indicators	Two 7 segment LED digital indicators, curing time in seconds.	Power ON Calibration 2 digit display (curing time in seconds).